PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)
(PCT Rule 44bis.1(c))

To:

ABELEV, Gary
Dorsey & Whitney LLP
250 Park Avenue
New York, NY 10177
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)*	
21 February 2008 (21.02.2008)	
Applicant's or agent's file reference	**IMPORTANT NOTICE**
186666/PCT	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2006/031275	09 August 2006 (09.08.2006)	09 August 2005 (09.08.2005)

Applicant
THE GENERAL HOSPITAL CORPORATION et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 82 70

Authorized officer
Ellen Moyse

e-mail: pt05.pct@wipo.int

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 186666/PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2006/031275	International filing date *(day/month/year)* 09 August 2006 (09.08.2006)	Priority date *(day/month/year)* 09 August 2005 (09.08.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant THE GENERAL HOSPITAL CORPORATION		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 12 February 2008 (12.02.2008)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Ellen Moyse
Facsimile No. +41 22 338 82 70	e-mail: pt05.pct@wipo.int

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2006/031275	09.08.2006	09.08.2005

International Patent Classification (IPC) or both national classification and IPC
INV. G01B9/02 G01N21/47

Applicant
THE GENERAL HOSPITAL CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Petelski, Torsten Telephone No. +49 89 2399-2441

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 11,24,27,28

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 11,24,27,28 are so unclear that no meaningful opinion could be formed *(specify)*:

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☐ no international search report has been established for the whole application or for said claims Nos.

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	14,19
	No:	Claims	1-10,12,13,15-18,20-23,25,26
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-10,12-23,25,26
Industrial applicability (IA)	Yes:	Claims	1-10,12-23,25,26
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Reference is made to the following documents:

D1: XP002415697; Jun Zhang et al.: "Full range polarization-sensitive Fourier domain optical coherence tomography"
D2: US-A-6 020 963
D3: XP002415698; Yonghua Zhao et al.: "Real-time phase-resolved functional optical coherence tomography by use of optical Hilbert transformation"
D4: XP002415699; Siavash Yazdanfar, Joseph Izatt: "Self-referenced Doppler optical coherence tomography"

Re Item III.

1. No opinion

(i) **Claims 27 and 28** contain storage media with software to perform a method of interferometry according to the method steps of **claims 15 and 26**. However, all those method steps like, e.g. providing light or combining light, are performed by optical arrangements like beamsplitters, detectors or waveplates without the interaction of software. It is unclear, how software should perform said method steps and therefore no opinion on novelty or inventive step can be given for **claims 27 and 28**.

(ii) It is unclear, what is meant by "positive" and "negative sections" of a (phase) delay in **claims 11 and 24**. This renders the claims so unclear that no opinion on novelty or inventive step can be given.

Re Item V.

2. Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of the following claims is not new in the sense of Article 33(2) PCT.

2.1 Independent claim 1

Claim 1 is formulated in such a broad manner that even a single polarizing beamsplitter would be novelty destroying. When placed in an interferometer behind whatever radiation source (also with changing spectrum), a beamsplitter (representing the first and second arrangement) is capable of providing polarized radiation to a sample and a reference and is at the same time capable of combining the orthogonally polarized radiation that is reflected back to the beamsplitter from the sample and the reference.

In particular, documents **D1**, **D2**, **D3** and **D4** disclose al features of **claim 1** (**D1**: p.6034, second paragraph - p.6037, second paragraph; fig.1,2; **D2**: col.2, l.60 - col.4, l.21; fig.2A,2B; **D3**: p.99, left-hand col., top - right-hand col., 2nd par.; fig.1; **D4**: p.2085, left-hand col., 3rd par. - p.2086, left-hand col., 1st par.; fig.1), because they disclose a first beamsplitter (**D1**: 2x2 coupler; **D2**: 30; **D3**: BS; **D4**: "50/50") that provides radiation to a sample (**D1**: "sample"; **D2**: target 90; **D3**: "sample"; **D4**: "sample") and a reference (**D1**: "mirror"; **D2**: mirror in "RSOD"; **D3**: 1110; **D4**: "reference") and a second beamsplitter (in **D1**, **D3** and **D4** identical with the first beamsplitter; in **D2**: 60) that combines the reflected or transmitted beams. In all documents, sample and reference beams contain two orthogonal polarization-components, which are both combined by the splitter. Furthermore, the spectrum of first and second radiation in **D1** changes over time (swept-source).

2.2 Independent claim 13

In addition to the first arrangement (see item 1.1), **D1**, **D2**, **D3** and **D4** disclose at least two second arrangements (**D1**: detectors D1 and D2; **D2**: detectors 75,75',76,76'; **D3**: detectors of port D and E; **D4**: detectors D1 and D2), which are capable of generating interference signals of whatever radiation is projected on it. In addition, said documents disclose a third birefringent arrangement (**D1**: phase modulator in reference path; **D2**: waveplate 120; **D3**: waveplate QWP; **D4**: Wollaston prism), capable of controlling a phase difference of the interference signals on the at least two detectors.

2.3 Independent claim 15

According to item 2.1, **D1** discloses all features of **claim 15**.

2.4 Independent claim 26

D1 discloses the use of an OCT-apparatus (p.6034, 2nd par. - p.6037, last par.; fig.1,2) comprising the steps of:
providing one first radiation to a sample and a second radiation to a reference (fig.1), wherein the spectrum of both radiations changes over time (swept source);
generating a first signal (on detector D1) and a second signal (on D2) different from the first signal (different polarizations are reflected differently by the sample) as functions of first and second interferences between one third radiation (back-reflected from sample) and one fourth radiation (back-reflected from reference mirror) and with an electro-optic phase modulator (electrically induced birefringence) specifically controlling, as a function of birefringence, a difference in phases of first and second interferences (the phase difference between sample and reference arm is changed or controlled by the phase modulator) to exclude $n\pi$ (at certain times, the polarization modulator creates circular polarization, and for equal length of reference and sample paths the interference signals will be out of phase by approximately $\pi/2$, knowing the implicit condition that the phase modulation depth is not bigger than $\pi/2$).

2.5 Dependent claims

The features that are added by the dependent **claims 2, 4-9, 10, 12, 16-18, 20-23 and 25** are known from at least **D1**:

claim 2: third arrangement is a detector
claim 4 and 18 :the detector modifies the radiation-signal into an electric signal as a function of predetermined efficiency data (A/mW)
claim 5: the efficiency data is based on a characteristic like the material of the detector,
claim 6: the detector is capable of sequentially obtaining a plurality of signals, determining statistical characteristics of the signals like average light intensity over

response time such that the predetermined efficiency data is derived, should the light intensity be known
claims 7, 8, 9, 20, 21 and 22: these claims define phase differences that depend on the characteristics of the sample and do therefore not limit the apparatus or method any further
claim 10 and 23: there is a phase delay between reference and sample arm and the topographic image is calculated by a computer as function of the delay and the signals of both detectors
claim 12 and 25: the sign and magnitude of the phase delay is measured and reconstructed by a computer
claim 16 and 17: both detectors detect interference signals between the polarization components of both beams

3. Inventive step

Dependent **claims 14 and 19** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(1) and (3) PCT), since they are merely minor modifications of the apparatuses that are disclosed in the prior art documents and which a skilled person would consider without the exercise of inventive skill, especially as the advantages thus achieved can readily be foreseen.

Re Item VIII.

4. Conciseness

Although the dependent apparatus **claims 1 and 13** and the respective method **claims 15 and 26** have been drafted as separate independent claims, they relate effectively to the same subject-matter and differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.